Complete Summary

GUIDELINE TITLE

Induction of labor.

BIBLIOGRAPHIC SOURCE(S)

American College of Obstetricians and Gynecologists (ACOG). Induction of labor. Washington (DC): American College of Obstetricians and Gynecologists (ACOG); 1999 Nov. 10 p. (ACOG practice bulletin; no. 10). [70 references]

GUIDELINE STATUS

This is the current release of the guideline.

According to the guideline developer, this guideline is still considered to be current as of December 2004, based on a review of literature published that is performed every 18-24 months following the original guideline publication.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Maternal and Fetal Conditions

- Abruptio placentae
- Chorioamnionitis
- Fetal demise
- Pregnancy-induced hypertension
- Premature rupture of membranes
- Postterm pregnancy

- Maternal medical conditions (e.g., diabetes mellitus, renal disease, chronic pulmonary disease, chronic hypertension)
- Fetal compromise (e.g., severe fetal growth restriction, isoimmunization)
- Preeclampsia, eclampsia

Other Conditions

- Risk of rapid labor
- Distance from hospital
- Psychosocial indications

GUIDELINE CATEGORY

Assessment of Therapeutic Effectiveness
Counseling
Evaluation
Management

CLINICAL SPECIALTY

Obstetrics and Gynecology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To aid practitioners in making decisions about appropriate obstetric and gynecologic care
- To review current methods for cervical ripening and induction of labor and to summarize the effectiveness of these approaches based on appropriately conducted outcome-based research
- To classify the indications for and contraindications to induction of labor, describe the various agents used for cervical ripening, cite methods used to induce labor, and outline the requirements for the safe clinical use of the various methods of inducing labor

TARGET POPULATION

Pregnant women requiring induction of labor

INTERVENTIONS AND PRACTICES CONSIDERED

1. Assessment of gestational age and consideration of potential risks to the mother or fetus
2. Patient counseling regarding the indications for induction, the agents and methods of labor stimulation, and the possible need for repeat induction or cesarean delivery
3. Cervical and pelvic assessment and assessment of fetal size and presentation
4. Cervical ripening

- Mechanical dilation methods including hygroscopic dilators, osmotic dilators (Laminaria japonicum), the 24-French Foley balloon, and the double balloon device (Atad Ripener Device)
- Administration of synthetic prostaglandin E_1 (PGE_1, misoprostol) and prostaglandin E_2 (PGE_2, dinoprostone) available in 2 forms: a gel and a vaginal insert

5. Labor induction
    - Oxytocin, misoprostol, mifepristone (RU 486)
    - Nonpharmacologic methods including stripping the amniotic membranes, amniotomy, and nipple stimulation
6. Continuous monitoring of fetal heart rate and uterine activity

MAJOR OUTCOMES CONSIDERED

- The effectiveness of available pharmacologic methods for cervical ripening
- Complications of various methods of cervical ripening and labor induction

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The MEDLINE database, the Cochrane Library, and American College of Obstetricians and Gynecologists' (ACOG's) own internal resources and documents were used to conduct a literature search to locate relevant articles published between January 1985 and February 1999. The search was restricted to articles published in the English language. Priority was given to the articles reporting results of original research although review articles and commentaries also were consulted. Abstracts of research presented at symposiums and scientific conferences were not considered adequate for inclusion in this document.

Guidelines published by organizations or institutions such as the National Institutes of Health and ACOG were reviewed, and additional studies were located by reviewing bibliographies of identified articles.

NUMBER OF SOURCE DOCUMENTS

Not stated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Studies were reviewed and evaluated for quality according to the method outlined by the U.S. Preventive Services Task Force.

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments also could be regarded as this type of evidence

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Not stated

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Analysis of available evidence was given priority in formulating recommendations. When reliable research was not available, expert opinions from obstetrician-gynecologists were used. See also the "Rating Scheme for the Strength of Recommendations" field regarding Grade C recommendations.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Based on the highest level of evidence found in the data, recommendations are provided and graded according to the following categories:

Levels of Recommendations

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

COST ANALYSIS

There is a significant cost difference for induction of labor between misoprostol and dinoprostone. The approximate cost of a 100-microgram tablet of misoprostol ranges from $0.36 to $1.20, whereas a dinoprostone gel kit ranges from $65 to $75, and the dinoprostone vaginal insert is $165. The cost would be increased further if oxytocin augmentation were needed. Moreover, dinoprostone is an unstable compound that requires refrigeration to maintain its potency, whereas misoprostol is stable at room temperature.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practice Bulletins are validated by two internal clinical review panels composed of practicing obstetrician-gynecologists generalists and sub-specialists. The final guidelines are also reviewed and approved by the American College of Obstetricians and Gynecologists (ACOG) Executive Board.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

The grades of evidence (I-III) and levels of recommendations (A-C) are defined at the end of "Major Recommendations" field.

The following recommendations are based on good and consistent scientific evidence (Level A):

- Prostaglandin E (PGE) analogues are effective in promoting cervical ripening and inducing labor.
- Women in whom induction of labor is indicated may be appropriately managed with either a low- or high-dose oxytocin regimen.
- Fetal heart rate and uterine activity should be continuously monitored from the time the PGE_2 vaginal insert is placed until at least 15 minutes after it is removed.
- High-dose PGE_2 vaginal suppositories may be used in the management of intrauterine fetal demise in the second trimester of pregnancy.
- Although the optimal dose and timing interval of misoprostol is unknown, lower doses (25 micrograms every 3 to 6 hours) are effective for cervical ripening and induction of labor.
- With term premature rupture of membranes, labor may be induced with prostaglandins.

The following recommendations are based on evidence that may be limited or inconsistent (Level B):

- Misoprostol use in women with prior cesarean birth should be avoided because of the possibility of uterine rupture

- The use of higher doses of misoprostol (50 micrograms every 6 hours) to induce labor may be appropriate in some situations, although there are reports of increased risk of complications, including uterine hyperstimulation.

The following recommendations are based primarily on consensus and expert opinion (Level C):

- For women with third-trimester intrauterine fetal demise, intravaginal misoprostol can be used to induce labor.
- Fetal heart rate and uterine activity should be continuously monitored from 30 minutes to 2 hours after administration of PGE_2 gel.

Definitions:

Grades of Evidence

I Evidence obtained from at least one properly designed randomized controlled trial

II-1 Evidence obtained from well-designed controlled trials without randomization

II-2 Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

II-3 Evidence obtained from multiple time series with or without the intervention. Dramatic results in uncontrolled experiments could also be regarded as this type of evidence.

III Opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees

Levels of Recommendations

A. The recommendation is based on good and consistent scientific evidence.
B. The recommendation is based on limited or inconsistent scientific evidence.
C. The recommendation is based primarily on consensus and expert opinion.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Overall Benefits

Safe clinical use of various methods of inducing labor

Specific Benefits

- Both PGE_2 preparations, the gel and the vaginal insert, have been reported to increase the probability of successful initial induction, shorten the interval from induction to delivery, and decrease the total and maximal doses of oxytocin needed to induce contractions.
- Misoprostol appears to be safe and beneficial for inducing labor in a woman with an unfavorable cervix.

POTENTIAL HARMS

Adverse Events Associated with Various Methods of Cervical Ripening and Labor Induction

- Stripping membranes is associated with bleeding from undiagnosed placenta previa or low-lying placenta, and accidental amniotomy.
- Uterine hyperactivity and fetal heart rate decelerations have been reported in association with nipple stimulation.
- Amniotomy used alone can be associated with unpredictable and sometimes long intervals before the onset of contractions, but is effective if combined with early oxytocin infusion. Other potential risks of amniotomy include prolapse of the umbilical cord, chorioamnionitis, significant umbilical cord compression, and rupture of vasa previa.
- Increased maternal and fetal infection have been reported in connection with the use of laminaria and hygroscopic dilators when compared with the PGE_2 analogues.
- The intracervical PGE_2 gel has a 1% rate of uterine hyperstimulation, while the intravaginal PGE_2 gel or vaginal insert is associated with a 5% rate. Maternal side effects of low-dose PGE_2 (fever, vomiting, and diarrhea) in contrast to high doses, are uncommon. The use of PGE_2 vaginal suppositories in the third trimester increases the risk of uterine rupture. The manufacturers recommend that caution be exercised when using PGE_2 in patients with glaucoma, severe hepatic or renal dysfunction, or asthma.
- Tachysystole and hyperstimulation are increased with a 50 micrograms or greater dose of misoprostol. The use of misoprostol in women with prior cesarean birth has been associated with an increase in uterine rupture. Misoprostol use for second-trimester pregnancy termination also has been associated with uterine rupture, especially when used with oxytocin infusion. An increase in meconium-stained amniotic fluid also has been reported with misoprostol use. The occurrence of complications with misoprostol use appears to be dose-dependent. Oral misoprostol is associated with fewer abnormal fetal heart rate patterns and episodes of uterine hyperstimulation

when compared with vaginal administration, but there are not yet enough data to support oral administration as an alternative method.
- The side effects of oxytocin use are principally dose related; uterine hyperstimulation and subsequent fetal heart rate deceleration are the most common side effects. Hyperstimulation may result in abruptio placentae or uterine rupture (a rare complication). Water intoxication can occur with high concentrations of oxytocin infused with large quantities of hypotonic solutions. The antidiuretic effect usually is observed only after prolonged administration with at least 40 mU of oxytocin per minute. A rapid intravenous injection of oxytocin may cause hypotension.

CONTRAINDICATIONS

CONTRAINDICATIONS

Contraindications to labor induction include, but are not limited to, the following situations:

- Vasa previa or complete placenta previa
- Transverse fetal lie
- Umbilical cord prolapse
- Previous transfundal uterine surgery

QUALIFYING STATEMENTS

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These guidelines should not be construed as dictating an exclusive course of treatment or procedure. Variations in practice may be warranted based on the needs of the individual patient, resources, and limitations unique to the institution or type of practice.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

1999 Nov (reviewed 2004)

GUIDELINE DEVELOPER(S)

American College of Obstetricians and Gynecologists - Medical Specialty Society

SOURCE(S) OF FUNDING

American College of Obstetricians and Gynecologists (ACOG)

GUIDELINE COMMITTEE

American College of Obstetricians and Gynecologists (ACOG) Committee on Practice Bulletins-Obstetrics

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Not stated

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

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GUIDELINE AVAILABILITY

Electronic copies: Not available at this time.

Print copies: Available for purchase from the American College of Obstetricians and Gynecologists (ACOG) Distribution Center, PO Box 4500, Kearneysville, WV 25430-4500; telephone, 800-762-2264, ext. 192; e-mail: sales@acog.org. The ACOG Bookstore is available online at the ACOG Web site.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

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